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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,167	06/08/2000	Brendan Larder	07691.0006	9773

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/31/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/589,167

Applicant(s)

LARDER ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/4/2002 has been entered.

Applicant's arguments and amendments filed 11/04/02 have been fully considered but are not completely persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 13-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must use the steps as set forth in the claims to practice the method of predicting resistance to a particular agent based

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upon the genetic sequence of a pathogen. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b), c) The specification provides guidance for using a particular and specific training set for one single pathogen (HIV) a limited number of genetic sequences of a limited segment of the genome of that pathogen (particular changes in particular enzymatic genes of HIV) and a limited number of specific therapeutic agents (AZT, etc. in table 3). Particular rules and training sets for these specific factors are set forth.

d) The invention is drawn to methods of predicting the resistance of any unknown pathogen to any unspecified agent based upon an unspecified training set with unspecified rules, error functions, testing data etc. The claims do not set forth any specific pathogen, agent, test set, or training set.

e), g) In the art of pathogen resistance, it is well known that every pathogen is very different, and does not respond the same way to every agent. Agents effective against a bacterial infection are not effective against a viral infection. Further, not all pathogens have been sequenced, and for those that have, those sequences are ever evolving in the face of today's antipathogenic agents. One of skill in the art would not be able to pick any pathogen and any agent and then look to the specification for how to design and practice the invention as claimed.. The specification does not provide information as to the important genetic sequences of every pathogen, and how those sequences or their changes are related to resistance to various agents. The specification does not provide training sets which are applicable to any or all known mutations of any or all pathogens that are related to resistance such that one of skill in the art would be able to practice the prediction of resistance on a new species or sequence of a pathogen. .

f) The skill of those in the art of molecular biology is high.

g) The claims are broad because they are drawn to methods of predicting whether any pathogen or variant of a pathogen would be resistant to any agent using neural net technology.

The skilled practitioner would first turn to the instant specification for guidance to practice methods predicting such resistance. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that the pathogens of the world are

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extremely diverse, having wildly divergent replication and infection strategies. The sequences of all pathogens are not so similar that direct correlations can already be made, and much is unknown about how certain mutations affect pathogen resistance. Finally, said practitioner would turn to trial and error experimentation to determine what pathogen to test, what the genetic sequences of those pathogens are, how they correlate to resistance to a particular agent, and then whether any predictive rules can be created that would work in a neural net technology. After such lengthy experiments, then one would need to prepare test sets to determine the accuracy of those rules, and then finally, after suitable rules and sets are written, the neural net must be trained and tested before one can even begin to attempt to predict whether a new, previously unclassified sequence would be resistant to a particular agent. Such studies would have to be repeated for every particular agent, and every particular pathogen. Such represents undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 and 13-20 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the actual steps required to “predict resistance” that must be performed to train the neural network by the trained neural net. Without such steps explicitly recited, the predicting step is entirely unclear as to how such predicting is to be performed. Applicant asserts that by way of amendments to the claims that the above rejection is overcome. However, the amendments do not reflect the actual steps necessary to

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predict resistance of a pathogen to a therapeutic agent. Final step © states that prediction is done using the determined genetic sequence and the trained neural network. However, the question remains of how to predict using these elements. What are the final steps necessary to use the sequence and the trained network? Does prediction involve comparison of sequence with the sequence of the trained network? Does prediction require other parameters? Without such steps, the claims remain unclear.

Conclusion

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, PhD whose telephone number is (703) 306-5439. The examiner can generally be reached between the hours of 9:00 am and 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
12/28/02


MARY K. ZEMAN
PRIMARY EXAMINER
